per milliliter. Allow the sample solution to stand 45 minutes before using.

[46 FR 2985, Jan. 13, 1981; 46 FR 15880, Mar. 10, 1981, as amended at 50 FR 19919, May 13, 1985]

§440.119 Dicloxacillin sodium monohydrate oral dosage forms.

§440.119a Dicloxacillin sodium monohydrate capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Dicloxacillin sodium monohydrate capsules are composed of dicloxacillin sodium monohydrate and one or more suitable diluents and lubricants. Each capsule contains dicloxacillin sodium monohydrate equivalent to 62.5, 125, 250, or 500 milligrams of dicloxacillin. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of dicloxacillin that it is represented to contain. The moisture content is not more than 5 percent. The dicloxacillin sodium monohydrate conforms to the requirements of §440.19(a)(1).

(2) *Labeling.* In addition to the labeling requirements of §432.5 of this chapter, this drug shall be labeled ''dicloxacillin sodium capsules''.

(3) *Requests for certification; samples.* In addition to complying with the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The dicloxacillin sodium monohydrate used in making the batch for potency, moisture, pH, organic chlorine content, free chloride content, crystallinity, and identity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The dicloxacillin sodium monohydrate used in making the batch: 10 containers, each containing not less than 500 milligrams.

(*b*) The batch: A minimum of 30 capsules.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Place a representative number of capsules into a high-speed glass blender jar containing sufficient 1 percent potassium phosphate buffer, pH 6.0 (solution 1), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Remove an aliquot and further dilute with solution 1 to the reference concentration of 5.0 micrograms of dicloxacillin per milliliter (estimated) for the microbiological agar diffusion assay and to the prescribed concentration for the iodometric assay.

(ii) *Assay procedure.* Assay for potency by either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive.

(*a*) *Microbiological agar diffusion assay.* Proceed as directed in §436.105 of this chapter.

(*b*) *Iodometric assay.* Proceed as directed in §436.204 of this chapter.

(2) *Moisture.* Proceed as directed in §436.201 of this chapter.

[39 FR 18976, May 30, 1974, as amended at 42 FR 59861, Nov. 22, 1977; 43 FR 2393, Jan. 17, 1978; 44 FR 10379, Feb. 20, 1979; 50 FR 19919, May 13, 1985]

§440.119b Dicloxacillin sodium monohydrate for oral suspension.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Dicloxacillin sodium monohydrate for oral suspension is a mixture of dicloxacillin sodium monohydrate with one or more suitable colorings, flavorings, buffer substances, and preservatives. When reconstituted as directed in the labeling, it contains the equivalent of 12.5 or 25 milligrams of dicloxacillin per milliliter. Its potency is satisfactory if it is not less than 90 percent and not more than 120 percent of the number of milligrams of dicloxacillin that it is represented to contain. Its moisture content is not more than 2 percent. The pH of the suspension, when reconstituted as directed in the labeling, is not less than 4.5 nor more than 7.5. The dicloxacillin sodium monohydrate used conforms to the requirements of §440.19(a)(1).

(2) *Labeling.* In addition to the labeling requirements of §432.5 of this chapter, this drug shall be labeled ''dicloxacillin sodium for oral suspension''.

(3) *Requests for certification; samples.* In addition to complying with the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assay on:

(*a*) The dicloxacillin sodium monohydrate used in making the batch for potency, moisture, pH, organic chlorine content, free chloride content, crystallinity, and identity.

(*b*) The batch for potency, moisture, and pH.

(ii) Samples required:

(*a*) The dicloxacillin sodium monohydrate used in making the batch: 10 containers, each containing not less than 500 milligrams.

(*b*) The batch: A minimum of 6 immediate containers.

(b) *Tests and methods of assay*—(1) *Potency*—(i) *Sample preparation.* Reconstitute the sample as directed in the labeling. Place an accurately measured aliquot of the sample containing an estimated 125 milligrams of dicloxacillin into a 100-milliliter volumetric flask. Add 20 milliliters of dimethylformamide and shake mechanically for 30 minutes. Dilute to volume with 1 percent potassium phosphate buffer, pH 6.0 (solution 1). The addition of dimethylformamide may be omitted if complete solution can be obtained with solution 1. Further dilute an aliquot with sufficient solution 1 to the reference concentration of 5.0 micrograms of dicloxacillin per milliliter (estimated) for the microbiological agar diffusion assay and to the prescribed concentration for the iodometric assay.

(ii) *Assay procedure.* Assay for potency by either of the following methods; however, the results obtained from the microbiological agar diffusion assay shall be conclusive.

(*a*) *Microbiological agar diffusion assay.* Proceed as directed in § 436.105 of this chapter.

(*b*) *Iodometric assay.* Proceed as directed in § 436.204 of this chapter.

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using the drug reconstituted as directed in the labeling.

[39 FR 18976, May 30, 1974, as amended at 42 FR 59861, Nov. 22, 1977; 50 FR 19919, May 13, 1985]

§ 440.125 Hetacillin oral dosage forms.

§ 440.125a Hetacillin chewable tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Each hetacillin chewable tablet contains an amount of hetacillin equivalent to 112.5 milligrams of ampicillin with suitable buffers, preservatives, binders, flavorings, colorings, and sweetening ingredients. Its potency is satisfactory if it contains not less than 90 percent and not more than 120 percent of the number of milligrams of ampicillin that it is represented to contain. The moisture content is not more than 2.0 percent. The hetacillin used conforms to the requirements of § 440.25(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The hetacillin used in making the batch for potency, moisture, pH, hetacillin content, identity, and crystallinity.

(*b*) The batch for potency and moisture.

(ii) Samples required.

(*a*) The hetacillin used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 30 tablets.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed for ampicillin in § 436.105 of this chapter, using the ampicillin working standard as the standard of comparison and preparing the sample for assay as follows: Place a representative number of tablets in a high-speed glass blender with sufficient 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to give a stock solution of convenient concentration. Blend for 3 to 5 minutes. Further dilute an aliquot of the stock solution with solution 3 to the reference concentration of 0.1 microgram of ampicillin per milliliter (estimated).